

"Yes." It says "Computer reports are acceptable under the final regulations," and then it gives a long explanation.

Does anybody have any problem with that?

[No response.]

DR. MONSEES: So electronic--it could be e-mailed, or it could be just that they can dial into the computer system and get it.

DR. FINDER: Right, but again, this is actually one where we thought about not putting the "Yes" in there because of the caveats that have to go along with it. It is not sufficient alone to just have electronic reports, because at some point, some of those reports are going to have to go to other systems, other doctors, who may not have the access. So they do have to have the capability of producing hard copy. That's why we didn't use just a simple "Yes."

DR. MONSEES: I have a question about this, and it may be just splitting hairs. I have access to path reports in my institution if I use my computer in such a way and basically check in with the pathology and then look it up in their system. It's different from receiving it as an electronic transfer to me, so unless I go and actively look it up, I may not get that path report. Are we assuming that somebody is going to have to get mailed this, or do they-- say, for example, a physician ordered a mammogram and didn't

get the report sent to him electronically or in a written format. Is he expected to have to look it up by dialing in?

DR. SICKLES: I think the intent of this--and we don't to this in our institution--even though our reports are available on line, we also send the hard copy--but I think the intent of this is that there must be some institutions out there who are so computerized, so heavily computerized, that they are paperless, and they just do not send reports, and physicians are expected every, single time to look up their findings in the computer. And actually, that's a good thing, because you save a few trees by not having to print out these masses of medical reports.

As long as they are available, and it is standard practice in the institution to do that, I think this is a very good solution, but in most institutions where it is practical, people still rely on paper because it is a habit.

DR. MONSEES: Yes, sir.

MR. PIZZUTIELLO: Bob Pizzutiello. I guess I would see that just a tad differently.

To me, the key word in the regulations says "provide." So in the example that Dr. Monsees brought up, I think that making a report available in a database for somebody to look at might not be the same as "provide." I certainly have no problem with providing some sort of electronic format report, but I have a concern that if we

just make data available in a database, we are sort of putting the onus back on the referring physician to find out the results, and I don't think that was the intent of this section. I think the intent is that the radiology provider needs to provide, do something active, to make sure that the referring physician knows what the result is.

DR. MONSEES: You state it better than I did, I think, but that's my point. I don't want them not to receive it because they didn't look it up.

MR. PIZZUTIELLO: Exactly.

DR. SICKLES: Is what you are getting at that in an electronic system like this, the recipient would have to somehow electronically sign off that they read it?

MR. PIZZUTIELLO: No, but I think it's the difference between sending an e-mail and just having a standard procedure that says within 24 hours, the reports are available on our system for your review. To me, sending an e-mail would be perfectly fine. That is "provide." But having it available in a database puts all the responsibility on the physician who is not regulated under this Act.

DR. SICKLES: I follow you.

DR. MONSEES: That was the distinction I think I was after.

Okay. Let's move on--

DR. LEE: I have a question.

DR. MONSEES: I'm sorry.

DR. LEE: I have a separate issue. The regulation kind of implies to me that a patient could be a self-referral. It says "when the patient has a referring health care provider or a patient has a named health care provider." It kind of sounds to me like some patients may be self-referrals. If so, what kinds of provisions are made when the patient is a self-referral?

DR. MONSEES: Those are covered.

DR. FINDER: There are several regulations referable to that type of patient. Basically, that patient has to get the official mammography report plus the lay summary plus, in those cases in which there is a need for that person to get further follow-up, the facility has to make arrangements so that they can get that follow-up, so they can be referred on.

So there are those requirements. However, there is no requirement that a facility accept self-referred patients. It is up to the facility. But if they do accept them, they have this added responsibility.

DR. MONSEES: Okay. Any others before we move on?

[No response.]

DR. MONSEES: Okay. At the bottom of page 17, "Mammographic image identification" and what needs to be on

there. The question: "We have limited space in our film flasher and do not want to use 'stick-on' labels. Can we abbreviate our facility name and address?"

And the answer says, basically, as long as the films can be returned to their rightful owner if they are displaced type of thing. This seems logical.

Does anybody have any comments on that?

[No response.]

DR. MONSEES: Okay. Let me confer with Dr. Finder about lunch. We're going to continue. It is 11:40. We're going to keep plugging on until he finds out.

"Quality Assurance - General." There is a long first part here, and then the question: "Can a facility designate more than one lead interpreting physician at a time?"

The answer is "No."

"Can a facility designate more than one quality control technologist at a time?"

The answer is "No."

"Must the lead and reviewing physician be listed as interpreting physicians at the facility?"

The answer is "Yes," but they don't have to read films in that institution, but they have to be listed.

Are there any comments on those?

[No response.]

DR. MONSEES: No comments. They read fine to me, too.

Why don't we just go a little bit further since they are ready for us at any time, and since we had a late break?

Let's get through--yes?

DR. DOWLAT: Could I have a clarification on this issue? There are several radiologists in our facilities who are interpreting. I am not quite clear about this. One of them has got to sign out, or all of them can sign out, or--I don't understand this.

DR. MONSEES: Okay. There are lots of interpreting physicians. That means that they are qualified to read mammograms under MQSA. Then, there is a lead interpreting physician at each institution who is responsible for the quality assurance process. And then there is a reviewing physician who does the audit and reviews the audit and so on, but those are what they are referring to. So if they have 10 radiologists, there might be only one lead interpreting physician who also serves as the reviewing physician; everybody else may be just qualified interpreting physicians.

Does that answer your question?

DR. DOWLAT: So when they send the report, they just sign out, but there is nobody referring to it for

quality assurance--

DR. MONSEES: Yes, yes. That's what it is.

DR. DOWLAT: Thank you.

DR. MONSEES: Yes?

MS. WILSON: I have a comment. For the quality control technologist, you may designate other technologists to perform the quality control test as long as the quality control technologist assumes overall responsibility for the test?

DR. MONSEES: That's correct. That's the way I understand it.

MS. WILSON: Could we have that added to the statement?

DR. FINDER: The answer to that is I'm not 100 percent sure, but I believe that that question is actually dealt with in previous guidance documents. I believe it is. And again, it is sometimes kind of hard to visualize what this entire thing is going to be once it is all put together, but I believe that your question actually was addressed in one of the previous documents, and when this is all put together, you will see a whole list of questions of which this will only be one. We don't want to lengthen these out by answering every possibility in each question. That's why it is not there. If it is missing in the other questions, we certainly can add it here, but I believe it

has been addressed.

DR. MONSEES: Okay. Let's do the "Records" part, and we'll stop when we get to the quality control tests other than annual.

So page 19, "Quality Assurance - Records." "The lead interpreting physician, quality control technologist," and so on. And then moving down to the question and answer, do we have any comments on these? I have one pertaining to the technique charts, and I'll just state it here.

The question at the bottom of that page: "Is it acceptable for a technique chart to simply state that the facility is using the unit in its fully automatic mode for all patients?"

The answer is "Yes," and I have a problem with that because of patients with implants, where you can't use the fully automatic mode with the implant in place; you have to use a manual exposure technique. So I don't think that that answer suffices.

Are there any other comments or questions?

DR. SICKLES: Still another reason to take out the "Yes."

DR. MONSEES: Okay. Yes?

MR. PIZZUTIELLO: The way I recall the format for technique charts that most facilities use, which is the one which is in the ACR manual, there is a header section which

describes the standard imaging procedures, and then there are places to put in specific techniques otherwise used.

The way I interpret this question is that most facilities in this situation would be using fully automatic or standard views, so maybe if we just say something like "standard views" or "routine views"--it might be better to say that. But I agree with the rest of the concept of this document, that if you don't indicate anything about the kVp, then if the fully automatic mode is not functioning properly, you have no way of knowing what to do, so you should not use the unit--which is the reason why I encourage facilities to say we use the fully automatic mode, but here is the approximate kVp mode that we would choose to use.

DR. MONSEES: Are there any other comments on this section?

[No response.]

DR. MONSEES: Okay. So we're up to the "Quality Control Tests - General/Other than Annual." I think we'll break for lunch, and we will resume promptly at 1 o'clock. See you then.

[Whereupon, at 11:45 a.m., the proceedings were recessed, to reconvene at 1 o'clock p.m. this same day.]

AFTERNOON SESSION

[1 o'clock p.m.]

DR. MONSEES: Welcome back. We are going to start on page 20, "Quality Control Tests - General/Other than Annual," and then we have some additional questions to interject.

So we'll start with the first question: "Under final regulations, must facilities chart the data for quality control tests, such as processor sensitometry or phantom image evaluation?"

Yes?

MS. WILSON: Patricia Wilson. It is my opinion that the status should be charted. I don't know how the inspectors would go through inspection, looking at each QC film for a year to determine if something were out of limits if they had not charted the status.

Also, trends--we are supposed to evaluate trends. It is very clear to see this if it is charged; if you are just looking at your strips every day, you could easily miss a trend.

DR. MONSEES: Please.

MR. PIZZUTIELLO: Bob Pizzutiello.

I have had experiencing looking at lots of facilities that have done exactly this--not plotted it and just written the numbers down--and in variably, you find

that numbers are written down every day, but no one ever really looks at the numbers to see if there was any allowable variation. At least if we plot them on a chart, it sticks out. Now, sometimes people still don't notice that, but I think that unless they are forced by regulation to permit people to not plot them, I think it is not in the interest of either the spirit of quality control and quality patient care to permit facilities not to plot them.

DR. MONSEES: It must be very time-consuming for an inspector to look at something that's not graphically displayed; when they come in and look at a year's worth of data, it must be very difficult.

Are there any other comments on that?

DR. FINDER: Just to make mention--obviously, you can tell from the answer--that we agree with the intent or the concept of charting. It's a question of what it says in the regulation and what we can mandate, and that's the issue here. I don't know how to get around it in terms of if somebody asks the question is it mandated, do you have to do charting. If you look at the regulations, it doesn't mention charting. It's kind of hard to force them to do it. We can recommend, we can strongly recommend. If you can come up with some better wording--

DR. MONSEES: Do you have any idea whether the individual States require it?

DR. FINDER: I couldn't answer that.

DR. MONSEES: Yes?

DR. NISHIKAWA: Bob Nishikawa. What is the clinic required to show--I mean, they just show the charted numbers; how do they prove that those are always within acceptable limits?

DR. FINDER: Well, when it's charted, it's much easier--

DR. NISHIKAWA: Yes, I know, but is it the onus of the inspector to find whether they are out of limits on a given day, or is it the onus on the clinic to prove that they are always within limits?

DR. FINDER: It's kind of a combination of both. Obviously, they have to be in limits in order to practice. But the inspector goes into check and make sure that is. Now, this obviously would make it more difficult for them to take a look and see.

DR. NISHIKAWA: One way I can see of getting around this is if you make it that the onus is on the clinic, then one easy way for the clinic to do that is just to chart it.

DR. FINDER: That's what we're recommending, and that's what everybody is--

DR. NISHIKAWA: Otherwise, you could make them do some statistical analysis or something like that.

DR. FINDER: Well, it's a question of what we can require. We're limited in terms of what the regulations say.

DR. SICKLES: Charles, I have a question.

DR. FINDER: Yes.

DR. SICKLES: Why can't the FDA as regulators decide that the only effective way to administer it is to require charting? Why does the word "charting" have to be in the statute for you to require it?

DR. FINDER: This is an issue that we have been debating and talking about and trying to go through our general counsel as to what, legally, we can say and what we can get away with, and this is still a matter of debate. We're trying to talk to them and see how far we can push this.

DR. SICKLES: Maybe if you could get a sense from the Committee about how the Committee feels about it, it might help you.

DR. FINDER: Well, we gathered before we came here that the general consensus would be that charting is the preferable way to go; everybody agrees to that, and it is now just a question of the legality of how far we can go in terms of requiring versus other methods that may possibly in the future be just as good or better. If we come down to hard and say charting is the only way, then we have said

charting is the only way, and there is no other method. So we also want to be careful about that. But everybody kind of agrees that right now, charting is the way to go.

DR. MONSEES: Go ahead.

MR. PIZZUTIELLO: Perhaps you could say something like, "Until such time as alternate methods that are either equal or better are shown, nothing has been shown to be as effective as charting." I think that's a fair statement.

DR. MONSEES: That's a fact.

MR. PIZZUTIELLO: And I think it also should be clear that even if you are unable to go in that direction, which is the preferred direction, then any kind of documentation that the facility might generate must indicate the acceptable variation in the data, essentially on each page because these things will turn into many, many pages, and if they don't write down at the top what the acceptable value of these numbers are, there is no chance that they will know that it is not within the acceptable limits.

DR. SICKLES: I think you could figure out a way to get around this in terms of requiring so much paperwork on the part of the facility that isn't charting that they are going to chart. I'm sure there are methods. The IRS knows how to do it, and I'm sure you can do it.

DR. MONSEES: Well, in addition, is it possible to require that they flag any time they are outside of certain

limits?

DR. FINDER: It's not in the regs.

DR. MONSEES: It's not in the regs. They don't have to do that?

DR. FINDER: Again, there's nothing in the regs that says they have to flag it. Obviously, they have to take action when they are outside that limit, and they can be cited if they don't. This is just a means to make it easier. Like I said, we are looking at this option, and this is what we have come up with so far as a draft proposal. We'll see where it takes us. But as I say, we have to stay within the regulations also.

DR. MONSEES: I suppose a facility that doesn't chart might find it unpleasant if the inspector went through every day of 365 days a year and wanted to look at each one, and it took them two days to go through it. That might be unpleasant enough to cause them to chart the next year.

DR. FINDER: We do say in the last sentence, "The use of charts will also serve to expedite the inspection process." I guess we could put another sentence in there, "And if you don't, the inspector will be there for two days."

[Laughter.]

DR. FINDER: That might work.

DR. MONSEES: Okay. I think we beat that one to

death.

"How should facilities retain QA/QC records for equipment (film processors and/or mammographic units) that were in use for a period of time between the previous MQSA inspection and the current inspection, and have since been retired from use and replaced with new equipment?"

The answer here looked okay to me. Does anybody have any questions on that one?

[No response.]

DR. MONSEES: "Must the QC records indicate the actual numerical result of the QC test (e.g. compression, fixer retention) or just whether it passes or fails?"

There is no "Yes" or "No" here. Did you notice that? Are there any questions or comments on this?

[No response.]

DR. MONSEES: Okay. Moving on to "Daily quality control tests," did we need to interject any of these, Charlie, into this?

DR. FINDER: Actually, there is no question for the daily except for the one that we have on this list of questions that I gave the Committee.

DR. MONSEES: Well, here is the daily at the bottom. "Film processors used to develop mammograms shall be adjusted...." I see, so there is no question with it.

At the bottom of page 20, it addresses daily, and

there are no questions pertaining to it, but there is an additional one on this other sheet. Charlie, which one is that? Do you want to read it?

DR. FINDER: Yes. Actually, there are several questions that we'd like the Committee to address. These were given out earlier to you to think about. The first one is "After a facility dumps its chemistry for purposes of using a new type, it usually re-establishes its operating level by performing a 5-day data plot average. During those 5 days, during which time the facility can continue to process mammograms, a) does the facility continue to plot the data on the processor chart; b) if the value, speed and contrast indices fall outside the limits using the existing or the old limits, is it a violation, or are they exempt from having to stay within the limits during the 5-day averaging period?"

In effect what this says is that normally, when you are doing your plot, you have to stay within a certain action limit; otherwise, you have to stop processing mammograms. However, once you switch to a new chemistry, it takes time to establish the new operating level. During that period of time, what is the facility supposed to do?

DR. MONSEES: Yes?

MR. PIZZUTIELLO: I think that it is important to remember that this is not the routine procedure, because

most of the time we do a crossover procedure on a single day, so that most of the time when these things occur, we know exactly whether the processor is in control or not.

My experience has been that when you have the occasional circumstance where you have to re-establish baselines for 5 days, you really don't know on day one or day 2 or day 3 where you are, because you have to average that data to find your operating levels. So therefore, it would seem to me to be impossible to really know whether you are in control or not until 5 days elapse. Therefore, it does not make sense for me to see a facility cited for not being within limits, because you cannot know what the limits are. And whether they plot them or just keep track of the numbers for 5 days is probably not very significant.

DR. SICKLES: We had this situation happen to us inadvertently, because the company that manages the processors by chance put the wrong chemistry into our system, and we didn't expect it, but they did it in the evening, and we came in in the morning, and everything was crazy, and we had to start over again.

Our solution to it was to plot it on a different-- not the same sheet, because it makes no sense plotting it on the same sheet--we started a new sheet. For the first 5 days, we just plotted it on a sheet, and that was just the 5 days. After the 5 days, it established the baseline.

During the 5 days, you don't know what is in or out, and you have to average it, so you accept anything for the first 5 days and hope for the best.

I don't know of a better solution, because you have to take the average to get your limits, as Bob said, and then you just start over again. You might want to emphasize, though, that if they do this, they start new sheets, not stay on the old sheets.

DR. MONSEES: Is this described in the ACR Manual, Ms. Butler, the new Quality Control Manual? I am trying to think if this is addressed in there.

MS. BUTLER: Penny Butler with ACR.

The issue of re-establishing operating level limits, new baselines, is addressed, but we do not address Dr. Finder's questions as to how we can determine on a daily basis while we are collecting this average whether the system is working within operating levels.

However, we have discussed this issue with FDA, and by default, by the nature of what you are doing, all your data points for that 5 days that you are averaging will fall within the operating levels when you go back and plot that. We don't really see this as a new problem. This is a situation that was in existence during the interim rules, and there are valid cases when you do need to re-establish operating levels, and it seems to have worked before.

DR. MONSEES: So the suggestions here would be concordant with what--

MS. BUTLER: That is correct.

DR. MONSEES: That's good. It's always nice when there is consistency. Thank you. Okay.

Are there any other comments on that?

[No response.]

DR. MONSEES: Okay, let's move on. Do you want to do Question 2?

DR. FINDER: Yes, why don't we do that. Another question that we had--and this is an example, obviously: "A facility has five mammographic units and two processors. Should they designate specific units to be used with a specific processor or can they mix and match units and processors? If they decide to mix and match, are there any quality issues they need to be aware of, or would they have to perform any specific additional QC testing?"

DR. DEMPSEY: This actually is exactly like our facility, and from a standpoint of preserving the mental integrity of all the technologists, you can't designate just one processor to be used with certain instruments. It has to be a mix and match. And the only thing we do is maintain separate records for each of the processors and follow them very closely and make sure that they both match in the morning, that they are standardized within limits to each

other.

That takes time to make sure the processors are matched. But in terms of separating units and processors, I don't think you can reasonably do that.

DR. MONSEES: We do the same thing, for what it's worth.

Do you have any comments on this? Yes?

MR. PIZZUTIELLO: I think the practice is consistent with the theory, that is, if you have shown that any individual processor is working properly with an individual mammography unit, and then you just compare the processors to make sure that they are comparable, it should not matter which processor you process any individual machine films from.

DR. FINDER: I would only add that there is no requirement that the two processors be within any limit here. That's the issue. If they were, that's one way to solve the problem, but let's say they are operating at different operating levels.

MR. PIZZUTIELLO: Well, I think a good practice would be exactly what has been previously discussed. If you wanted to put something in guidance that went in this direction, you could say that you need to use an individual processor for an individual mammography unit unless you demonstrate that the processors are compatible with one

another. That would be sensible.

DR. DEMPSEY: In your guidance, you could just say it stands to reason that if there is a mix and match that the processors should be within tolerance levels of each other in order to standard film quality for density and contrast.

DR. SICKLES: There is another issue here. Some practice, especially busier practices, will maintain a backup processor that they don't usually use for mammography but which is kept in compliance with MQSA standards in case the regular processor goes out of alignment, so that they don't have to call in the repair person and get him in right away before they can do the first patient when they've got 50 patients scheduled. They keep a second processor going, although they don't use it routinely, but then on days when they need to use it, they make sure that their QC is correct, and that's a variant of this that you may want to put into the guidance, because I suspect that's used a lot also.

MS. WILSON: I agree that we should be able to mix and match processors to equipment; otherwise it will be very difficult to equalize the volume of films going to both processors. Also, I think we should consider recommending that the aim between the two processors for the MD and the DD be less than .20 difference between the two processors.

I think that if you see a difference higher than that, you will find films processed out of Processor A that would be lighter or darker than Processor B and could affect the clinical outcome.

DR. MONSEES: Good point.

Are there any other comments on that?

DR. FINDER: Let me just clarify in my own mind. If the processors are within the tolerances that we are talking about, then they can mix and match as they like. If they are not within the tolerances, then what should they do? Should they run tests--let's say the phantom test--weekly instead of in this case, they would run five films from the five units through each of the processors individually, so they would run 10 phantoms--is that correct?

DR. DEMPSEY: I can tell you from a practical standpoint--this is the way we operate--that if we find that one of them, or that they are not within tolerance--when the numbers are charted, it becomes very clear which processor is out of tolerance--and then we have to do something to rectify that particular processor. Usually, there is no great mystery as to which one is giving you the problems if you chart your processor data daily. And then we just have the people come and work on that one processor until we get it back in tolerance--following the standard procedures to

do that.

MS. WILSON: I think you would have a QC chart for each processor, use one box of QC film for both processors--the same box--establish your aim for each processor so that if the speed for Processor A were 1.30, the speed for Processor B had to be within that range, and then you would simply chart them every day, and if you were within limits, I think you could use the processor.

I think you would need to use the same sensitometer and densitometer for both processors to keep as many variables the same as possible.

DR. MONSEES: Which moves me to the next question here which is an add-on question on another sheet: "How should a facility handle the matter of daily processor QC testing when either their sensitometer or densitometer is unavailable, malfunctioned, or out for repair?"

Yes, sir, do you have an answer there?

MR. PIZZUTIELLO: In fact, I just addressed this question with FDA back in about January, and I wrote a suggested procedure which got shuttled around through some different folks at FDA who basically thought it was a good idea. I thought it might be helpful to publish it in "Mammography Matters," and I was told that "Mammography Matters" was filled up for the current issue.

But the gist of this procedure was to take a

phantom, use a manual technique, use film from the QC box so you can compare it, and look for consistency of optical density taken with a manual technique, so you eliminate the variability of the automatic exposure control and use that for the period of time that your sensitometer is not available.

I have a written procedure, and I have another copy here if anybody would like it at FDA; it might be a helpful way to do it. We have used this with our clients for about 4 years, and it has been helpful whenever it is needed, and it is needed from time to time.

DR. MONSEES: Any comments on that?

Yes, ma'am?

MS. WILSON: I think there are several things we could do. I think we definitely need something in place for a facility. If a facility cannot process any images for however long your sensitometer is out--they recommend that eve other year, you send it in for recalibration--it is very difficult. Obtaining a loaner sensitometer is practically impossible, and even if you get a loaner, unless you have had time to do a crossover between the two sensitometers, it doesn't give you a lot of information.

I agree that we could use the phantom test. Also, we have been experimenting at our facility with freezing film, pre-stamping the sensitometric film and freezing it,

and taking it out on the day of exam. Every morning, it took an hour before the procedure to let it thaw, and we used a net filter process, and we did not find a lot of variation in the film.

I would recommend that FDA pursue this. If everybody had a process in place for the times that occur every other year when you send your equipment in to be recalibrated, then perhaps on the days when you come in and you drop your sensitometer, and it shatters, there might actually be a loaner out at Exrite [ph.] or some company that they could loan you to get you through this time frame.

DR. MONSEES: Yes?

MR. PIZZUTIELLO: If I understand this correctly, Patricia, you are talking about presensitized film, right-- you flash it in the sensitometer and then freeze it?

MS. WILSON: Yes.

MR. PIZZUTIELLO: Okay. I want to make sure that's clear. Orhan Suleiman has done a lot of research on that, and I can't remember--he and I were talking about this about 6 months ago--he is in the audience--maybe Orhan could address it rather than my guessing. He is the expert.

MR. SULEIMAN: Orhan Suleiman, FDA.

Yes, we have done a lot of work regarding pre-exposed films over the years, and it keeps on coming back up. The latent image on the film is not stable; it could

increase in density, it could decrease in density, it could remain constant. It is vulnerable to environmental conditions, time and so on. So we strongly do not support using pre-exposed film. It causes more problems than it solves.

I think the phantom test is a very valid, simple backup, which Bob Pizzutiello was mentioning.

On the issue with the freezing and so on, it does keep coming up, but it introduces so many other variables--the conditions you expose the film, the storage conditions, the freezer, and so on--and even then, we have had some reports from the field from facilities where the phantom test has picked up problems, and the pre-exposed films have not, when in fact there have been changes.

So I think it would be good science to stay away from that unless there are some very good studies that I am still not aware of that validate that procedure.

DR. MONSEES: Thank you.

Yes?

DR. NISHIKAWA: I have a question for Bob. What you address, I think, is that your sensitometer doesn't work. What do you do if your densitometer doesn't work?

MR. PIZZUTIELLO: The densitometer is tougher; they tend to fail less frequently, I think, than the sensitometer. You can always substitute a visual check of

density for a densitometer if you are comparing two densities.

I want to say that the studies show that the human eye on a good observer, to match up strips side-by-side, can detect .03, .05, something like that. So it's on the order of what we're talking about for a backup procedure. So in the absence of anything else, I would be looking at that. But there is a better availability of backup densitometers because they tend to be available in other places in hospitals. Sensitometers are available nowhere else.

DR. MONSEES: Is there any other deaccession on this matter?

[No response.]

DR. MONSEES: Okay. Do you have any others that pertain to the daily?

DR. FINDER: No.

DR. MONSEES: So we'll move on to the weekly quality control tests on page 21 near the top.

"Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly," and then they mention what those are.

Question: "If a weekly QC test is performed every week but not every 7 days, can the facility be cited?"

The answer is "No," and then it explains why.

Question: "When performing the weekly phantom QC test, should we use film from the box currently being used to produce clinical exams or film from the box used for quality control purposes?" And it describes the answer there--it is lengthy.

Does anybody have any disagreement with any of those?

Yes?

DR. SICKLES: I don't have a disagreement. I just wonder whether the long answer at the bottom of page 21 is sufficiently instructive either to the facility or, for that matter, to the inspector to know whether when a facility came to the conclusion that a change was due to different film emulsions that they went through the right procedure. All it says here is "check the whole imaging chain". What do you mean?

DR. MONSEES: Well--

DR. SICKLES: I know what you mean, but I am not sure that an individual facility would know or what an inspector would look for to be assured that a facility did the right thing, and it might be helpful to be a little bit more forthcoming in the explanation.

DR. MONSEES: I don't know where you draw the line, because this isn't a QC manual; it is guidance.

DR. SICKLES: I know.

DR. MONSEES: What do you think, Charlie--yes?

MR. PIZZUTIELLO: One of the things that we think is important in the practice of medical physics is being available to help facilities when these sorts of sticky questions come up. So what we have advised our folks to do is if something like this comes up, call us. Then, we can look at the data, ask them to try this or that and kind of use some professional judgment to say what test you need to do, because while you want to look at some aspects of the imaging chain, you don't really need to look at all the aspects of the imaging chain and so on.

So how would it be to say something like "Contact your medical physicist to consult as to what would be appropriate to do"?

DR. SICKLES: Yes, that's fine, and maybe the guidance could be that specific--contact your medical physicist and document that you have contacted him--something like that. Just write down, "Medical physicist called. Answer--yes/no."

Facilities tend to function better and with a lot less concern if they know that the procedure they have chosen to use is acceptable than if they are guessing as to whether it might or might not be acceptable. And it is much more likely to be followed if this is laid out, this is what you do, and they do it.

DR. MONSEES: Okay, let's move on, then, to the next question: "When evaluating the phantom QC test, must the technologist and the physicist correct for artifacts?"

It says that you are supposed to use the same scoring method as the accrediting body.

Do we have any disagreement there? Yes?

MR. PIZZUTIELLO: I don't particularly love the phrase "correct for artifacts". How about "adjust the score for artifacts"?

DR. MONSEES: Okay, "adjust the scoring"--because to "correct for artifacts" would be to get rid of them. Okay.

The next page, at the top of page 22, they address how they do "phantom images using the AEC mode rather than the Full Auto mode that we typically use for patients. Is this acceptable toward meeting the requirement?"

And they say that you should do them under the same typical clinical conditions.

Is there any disagreement with that? Yes, sir.

MR. PIZZUTIELLO: This is a problem for a number of units that have automatic kV-type function. the idea is that the algorithms in this equipment somehow determines what radiation is going to be needed to meet its criteria, chooses the kVp and then, eventually the mAs. But somewhere in any algorithm, there has to be a decision point that

says, well, below this point, we pick 25 kV, and above this point, we pick 26 kVp.

Whether you do an image of 25 or 26 kV probably doesn't make very much difference--we talked about that before. But in some of these machines, if you take 10 consecutive exposures in the Automatic mode, five of them will come out at 25 kV, and five of them will come out at 26 kVp. So what we have suggested to some of these places is to say if you can't alter the calibration so that the decision point doesn't happen right at that 4.2 cm phantom, which is what they use, then we would accept using a fixed kVp for their phantom images.

An alternative which was suggested by our local inspector was that facilities keep two separate plots--one if the phantom comes out at 25 kV, and one if the phantom comes out at 26 kV. Now, the reason why you might need this is because if you're shooting your phantom at 26 kV, and it takes 70 mAs, then at 25 kV, it might take 100, so your mAs is out of the range.

However, I think that that's really excessive to have to keep two separate plots and figure out which one you are in. I personally think that because this is a fundamental way that automatic exposure controls are designed, I don't have any problem with this one particular time when we don't do the phantom exactly the way the

facility does it. When the medical physicist comes in and does his annual survey, we're checking for consistency of the photo timer [ph.], and we will understand this. So I would see it differently than the way it is written here.

DR. MONSEES: Yes, Ms. Butler?

MS. BUTLER: Penny Butler, ACR.

I would like to agree with Bob Pizzutiello regarding this. In fact, in the Quality Control Manual, we don't specify for this test that it be done, for example, in the Full Auto mode; all we do is specify that the exposure uses a technical factor, and then we go on to specify target, filter, kVp, grid, density, control settings, et cetera, currently in use for a 4.2 cm breast. So if a facility normally uses Full Auto mode, and they know for a 4.2 cm average density breast, they typically give a 25 kVp, then we would suggest that they would manually select 25 kVp in the AEC mode to monitor this.

This addresses the issues that Bob is bringing up in terms of if we are also trying to monitor the mAs and look for deviations in mAs, we can do it on a single chart and not have to create multiple charts to do that.

DR. MONSEES: Just as somebody who looks at things as a black box sometimes, not fully understanding, is there a way by doing that that you are bypassing something that is important that could go awry, where if you tested it in this

way, and then you were doing patients using Fully Automated, is there something that could have gone wrong that you would not detect using this method of QC? Is there something that could happen in there? Could something happen to the algorithm?

MS. BUTLER: The medical physicist will pick that up on an annual basis; on a daily basis, I don't know.

MR. PIZZUTIELLO: Technologists get very familiar with what the technical factors are on a piece of equipment, and if they have always gotten 25 or 26, and all of a sudden the machine starts going for 27 or 28, any good technologist will immediately pick that up--not in a single patient, but if it becomes a pattern, I would say they would pick that up. So it wouldn't be specified in the QC test, but I think an experienced technologist would know the difference.

MS. BUTLER: And also, I believe that that may be reflected in a change in mAs if they do this with a fixed kVp technique.

DR. MONSEES: All right. Shall we move on, then?

"If the OD for the weekly phantom test falls below 1.20, must the unit be recalibrated, or can we adjust the density setting to obtain a 1.20 OD?"

There is a lengthy answer there, and then a follow-up question to that.

I presume you are the one to answer this; is that

correct?

MR. PIZZUTIELLO: I think this is pretty good. One thing I would like to add, because we are trying to do some guidance here, is on the first item. The most common reason why the density changes is because they are not consistent with the position of the automatic exposure control sensor. So if we just put a little phrase at the end of the first one, "ensure that the phantom is exposed using typical clinical conditions, especially the position of the AEC sensor should be consistent from time to time," that will eliminate 80 percent of this problem.

DR. MONSEES: Are there any other comments there?

[No response.]

DR. MONSEES: Okay. And then there is a follow-up question down at the bottom of the page. It's the same answer; it's the cut-and-paste. But is it the appropriate one for the little difference in the question?

That's okay. All right. Then, the other thing that has been discussed previously, and then there is a question: "Must the weekly phantom test be performed for all image receptor sizes?" and the answer is "No."

You are going to perhaps miss grid lines if you don't test it, if the grid is not operating right. What else could possibly be missed? And you should see those on the clinical images, but is there anything else that could

be missed if you don't test both sizes?

MR. PIZZUTIELLO: There is nothing else that comes to mind from an equipment point of view. The automatic exposure control is tested by the medical physicist and so on. But it is also important to remember that it is very difficult to do this in practice, because the batch of film that you use for the 24-by-30s is very typically a different emulsion number than the 18-by-24s, so you almost guarantee that you are going to find some difference in the density value that you measure just due to the emulsion differences.

So I think it is probably just fine the way it is.

DR. MONSEES: Okay. "Must the interpreting physician evaluate the weekly phantom QC test?"

The answer is "No" to that, and I think that is pretty clear in the regs. Does anybody disagree with that?

Please come to the microphone and say who you are.

MR. GALKIN: Ben Galkin, Institute for Mammography Research.

I have a question with regard to page 22, Item 3, where it says "If the mAs has changed by more than 15 percent, the medical physicist should be called." If I recall correctly, there is nothing in the regulations that requires mAs to be tested. It was eliminated in the regulation as compared with the ACR manual.

What I'm saying is that people are not required to

record mAs anymore.

DR. MONSEES: And you are alluding to using--

MR. GALKIN: What I'm saying is that this particular method of correction cannot be applied.

DR. MONSEES: Right. I understand what you are saying. And in fact Ms. Butler mentioned the mAs as well. Is that true that it is no longer in there? Do you remember?

MR. PIZZUTIELLO: I honestly can't say that I recall, because every facility that I go to does record the mAs because it is good practice, it is in the ACR manual because it is a good thing to do. And without that, I don't know how you know if your machine is working or not--but whether it's in the reg or not, I'd have to defer to somebody else.

MR. GALKIN: I agree with you that it's good practice, but I think it has been eliminated from the regs.

MR. PIZZUTIELLO: It's a good question. I don't know the answer.

DR. MONSEES: So if you are using the template sheets from the manual, it is on there.

MR. PIZZUTIELLO: Correct.

DR. MONSEES: But if you are not a plotter, you may not be using that sheet; right? Is it in there, Charlie? Is it in the regs? Dr. Galkin may be right.

DR. MOURAD: Wally Mourad, FDA.

It is not in the regs that you have to plot the mAs; that's correct. But I think the issue in the question is not whether the mAs drops or goes up above the limits. The issue is if something else goes out, then it is asking you to check the mAs as a good practice. So I don't see the issue.

Which question are we referring to here?

DR. MONSEES: At the bottom of page 22. And it's actually halfway up the page as well. It is item 3, "Check the function of the mammography unit by comparing the mammography unit's current mAs output with values obtained for previous phantom images," and so on. But if something is wrong, and you haven't recorded it before, what is your baseline?

DR. MOURAD: Okay. But I guess a good guidance practice is to record that even though it is not required in the regs.

DR. MONSEES: Right. If, suddenly, you have a problem, and you have no baseline.

DR. MOURAD: Correct. What I am saying is that it's a good practice to actually record it even though it is not required in the regs.

DR. MONSEES: Yes, right. Okay. I don't know how to handle that, but--

MR. PIZZUTIELLO: It does say "should" in the text.

DR. FINDER: This is not a requirement. This is one way. Obviously, this will work for facilities that have been recording the mAs at various points during the course of the year. The question is if a facility hasn't been doing this, what are they going to do. Well, this suggestion won't work for them unless they go back perhaps to their physicist's survey report and use that value or values there.

Again, guidance is a way or ways of meeting the requirement, not necessarily the only one, and if somebody is not recording the mAs, they can come up with a different method to do it, but I'm not exactly sure what that would be.

DR. MONSEES: Okay. Shall we move on?

Did somebody else have a comment--yes? Did you want to interject something else? We did the all receptor sizes and whether the interpreting physician must evaluate the QC, and then we had the question from the audience.

We are up to "Semiannual quality control tests." Which one do you want to add in?

Okay. The weekly phantom--do you have any others on that one?

Another add-on issue was one of the items raised

by the Institute for Mammography Research--not all of these items, but one of them. Which one is it, Charlie?

DR. FINDER: It's this entire handout.

DR. MONSEES: Okay. Do you want to address that, the handout that came from the Institute for Mammography Research?

MR. PIZZUTIELLO: Yes.

DR. MONSEES: May I just say something? Don't talk about Item 4 yet for the demonstration program, because that does not pertain to this part--but the other part. Okay.

MR. PIZZUTIELLO: We have received copies of a letter that was written to FDA from Institute for Mammography Research, Ben Galkin's group, and he raises the question, the way I understand it, that he is concerned about the action limits.

There is a requirement in the regulation that says use a contrast disk, and your values should not change by more than plus or minus .05 OD from the established value. And the regulation says you don't have to necessary use any particular contrast disk, but the regulation does specify the action limits.

So Dr. Galkin says, well, if that's the case, then what would prevent a facility from using a different contrast disk that's much less sensitive to detecting

problems, because then the results will always be within plus or minus .05. And I don't see anything in the regulation that says otherwise. I don't know of anybody who would willingly do that. There may be some folks who could choose to do that, but I don't see that as a big issue without going back and changing the regulation to specify the phantom that was used. But that's not the style of the final regs. The style of the final regs is to specify as little as possible, and only specify the outcome.

The second part of his concern says, well, what if there is a better phantom available, a better version of this test, for which the .05 OD might not be the correct tolerance limits. And the way I would see it is if that were the case, the group that would espouse that approach should write a letter to FDA and request an alternative standard saying "This is what we propose; here is what is commonly done with a 4 cm acrylic disk and these tolerance limits, and here is how our proposal is equivalent or perhaps better than the one that is typically done." My experience with FDA has been that given that kind of documentation, they might seek some outside opinion and probably would respond favorably, because that's the intent of allowing the alternative standard.

DR. MONSEES: Okay. This was handed out and sent to the panel members in advance. Does anybody else have any

comments on the proposed solution to this by Mr. Pizzutiello, or the handout itself?

Yes?

DR. SICKLES: Only a brief one. I agree with that approach. That seems very, very sensible. Certainly if an alternative standard were to be requested that used a different schema, then they would have to document clearly what the new action limits would be. According to the data they supplied, the old action limits would not work at all, and they would have to come up with new ones that are not in this document, so they would have to establish some that would convince the FDA that it was at least equivalent, if not better--and presumably, you can do that.

DR. MONSEES: Right. Would you like to comment on whether you consider this an acceptable approach?

MR. GALKIN: Actually, when I started with the FDA on that, I did ask for an alternative. The problem is that it goes beyond just using the particular object. The positioning of the object which is also important. The current method of doing it is to put the 4 mm acrylic disk on top of the phantom, but if you use a 4 mm or some other object alongside the phantom, you're going to get an entirely different result. Not only that, but they are based in with the regulation again, which does not specify the 4 mm disk. It says "a test object." That could be any

test object.

The problem with asking for alternatives would be that you could ask for myriad, lots of different alternatives, depending on what particular facility wants to use what particular object and where they want to position it.

So the way the regulation is written now, reporting out in the letter, is that that particular action limit is not appropriate for the way the regulation is written. And what we ask the Committee to do is consider other ways of approaching a particular problem without changing the regulation, because I understand trying to change the regulation is a long, drawn out procedure.

DR. MONSEES: Do you have any suggestions?

MR. GALKIN: Well, I made one in the letter, and that would be to allow the particular medical physicist in the facility to establish action limits for the particular test that he feels are appropriate for that facility.

In the letter, I suggest one way of doing that, but there are other ways of doing that, and I suggested one object, but I am sure there are other objects. The way the regulation is written, there is no limit on the number of objects or how they could position or where they could be used or how thick they could be or what material they could be made of. So we have analyzed the problem, and I don't

think that any one number would be appropriate for the way the regulation is written.

So I am suggesting that as long as the test is more sensitive than the ACR test, the phantom disk method, that the facility only be required to validate that and validate with data that is generated by the medical physicist or perhaps by the supplier of the test object. That way, you will get around the problem of specifying a number with the various kinds of objects that could be used and the various positions they could be placed in, short of changing the regulation.

DR. MONSEES: Would you like to speak to that?

MR. PIZZUTIELLO: I'm not sure that we are saying anything really different, except that it's not a question of a facility determining the equivalence of a different phantom. I think that that needs to go to FDA as an alternative standard, and probably the best way to do that would be to have the person who is the most familiar with that product make the case, which would be the designer or the inventor of it.

So I don't really think that as a medical physicist--and I do quite a lot of mammography physics--that if I had a small experience with a different test object, I could generate enough data to really show equivalence. If I could, then I would probably write to FDA and ask can I get

an equivalence--an alternative standard approved.

So whether the physicist requests the alternative standard or whether the manufacturer does, I don't think is very important. I think it is important, though, that it go to FDA, because otherwise you could wind up with a variety of things out there that really have not been properly looked at.

Having said that, we're talking about one of the easiest tests out there. We're talking about a little piece of plastic that doesn't cost any money--the only thing you could buy in medical imaging for \$4; right--putting a piece of plastic on an image and taking two measures of density, and that is what meets the requirement. So facilities that want to do better, that may come up with a better system, by all means let them apply for an alternative standard, but I don't think there are going to be lots and lots of requests out there.

MR. GALKIN: I agree with everything you say, but the problem is that that test is not sensitive enough to detect wide ranges in exposure parameters. That has been shown and reported. You could get a 10 kV variation and still not be able to detect it.

MR. PIZZUTIELLO: I don't think that that is what that test does. The test is really not show kV, because we know that kV is not a very sensitive predictor of contrast

in an image. The most sensitive thing is probably the film processing, and it is really good at that, and we have seen lots of examples where the contrast disk says something is not right, and you find that there is a problem with the clinical film that wasn't present on the QC film, and that's why it doesn't show up in the processor sensitometry, but it is detected on the phantom image.

So I agree that it is not very sensitive to kVp, but there are other factors that affect the contrast much more so than kVp.

MR. GALKIN: But if you are not recording mAs, and the regulation does not require to record mAs, and it is not sensitive to kVp, so you are in compliance with a 10 kVp variance, and you have no problem. I mean, that's not the intent of the regulation. It's different from the intent of the ACR. The intent of the regulation is to anticipate problems with the equipment, not to just read density. And if the equipment is not functioning properly, and the test doesn't show that, then the test is not doing what it is supposed to do. That's what this is all directed at.

One other observation here is that since the regulation is not specific to a particular test object, any facility could use any test object without requiring an alternative according to the regulations. So I am suggesting that the Committee consider that problem, and I

don't think the alternative is the answer, because I started that a couple years ago. The alternative is fine except that if you change the model, or if you have many models, then you have to get an alternative for each and every model; so if you have two or three or four manufacturers out there who are doing various things, you have to get an alternative for each one of those.

DR. MONSEES: Thank you.

Do you have any follow-up comments on that?

MR. PIZZUTIELLO: No.

DR. MONSEES: Does anybody on the panel have any follow-up questions or comments on that?

[No response.]

DR. MONSEES: Okay. Now we move to "Semiannual quality control tests." Darkroom fog; screen-film contact.

"Must the screen-film contact and uniformity of screen speed tests be performed on new cassettes prior to clinical use," and must the medical physicist perform the tests.

And then we have a long answer preceded by a "Yes."

Does anybody have any comments on that?

MR. PIZZUTIELLO: Our discussion at lunch notwithstanding, the word "Yes" might not be the right way to start that, because I think it is very nicely specified

about two-thirds of the way down that if you get new cassettes, then the QC technologist is really not acting in the context of the annual physics survey. That person is acting as a QC technologist and can do the test in consultation with the medical physicist.

I support that 150 percent.

DR. MONSEES: Okay. Yes?

MS. WILSON: I agree. I would also like to address the darkroom fog issue. In Guidance Document 1 with regard to the backup processor, the only comment that is made is that you would establish a QC aim, and you would do a QC test on the day you needed to use the backup processor.

I would like to see added to this document that you would also need to do a darkroom fog test on the backup processor and a hypo-retention test. Without these two tests being performed on the backup processor, you could process films that were fogged, and you could also process films that would not have a retention value if the fixer retention rate were incorrect. I see this nowhere in the document guidance, 1, 2, or 3.

DR. FINDER: Actually, that's an issue that we are dealing with in terms of fixer retention, and we are looking at ways to address that. I am interested in what you meant by "darkroom fog." If you are using the same darkroom that you were using for your other processor, would you have to

do a new darkroom fog test, or is it just a separate--

MS. WILSON: Just a separate processor.

DR. FINDER: But a separate darkroom.

MS. WILSON: A separate darkroom.

DR. FINDER: Okay. That I can understand.

MS. WILSON: Which many facilities have two completely separate darkrooms.

DR. FINDER: Okay. This basically comes to the question in fact that we had in alternative standard which we talked about earlier, which was do you have to do the weekly phantom on weeks when you are not doing mammography. And I think we can extend that to these types of tests, too, and transfer that over to a backup processor or any processor that is not used for a long period of time, or a darkroom that isn't used for a long period of time; that if you haven't done the standard test, according to the time frame associated with the regs, that before you use it for the first time, you have to perform the test. So that would be a corollary to the other one.

DR. MONSEES: Are there any other comments here?

[No response.]

DR. MONSEES: All right. So we move to "Compression device performance" on page 24.

"What are the compression device performance requirements prior to 10/28/02?"

And then, "Several mammography units have initial compression devices that generate more than 45 pounds of pressure. Will they have to be replaced or modified after that date?"

Does anybody have any comments on the guidance that is given there, those two answers?

[No response.]

DR. MONSEES: Okay. Do you have any other add-ons to the semiannual before we move to the annual, Dr. Finder?

DR. FINDER: No.

DR. MONSEES: Okay. "Annual - Quality Control Tests."

The AEC, kVp, focal spot condition, and the rest on the next page are all written out here, and then the questions that come with that.

Is this redundant--"Must the screen-film contact and uniformity"--

DR. FINDER: Yes.

DR. MONSEES: It is redundant.

Then, at the top of page 27 is also the same thing; it's a cut-and-paste situation.

Then, we move to "System artifacts." Is that not right? Did I miss something?

DR. SICKLES: Page 26 is a repeat question.

DR. MONSEES: Page 2 is a repeat question. That's

what I was just referring to. But Dr. Finder tells me I missed something on page 25.

"Does this regulation require that kVp be within 5 percent agreement with an absolute standard"--is that what you're talking about? Yes. I missed that. We did the one above--

MR. PIZZUTIELLO: Excuse me. Can I make a comment on the one above?

DR. MONSEES: Yes.

MR. PIZZUTIELLO: The one above was about multiple AEC detectors.

DR. MONSEES: Right.

MR. PIZZUTIELLO: And the most common clinical case of that is one manufacturer where there are different AEC detectors for different size buckies [ph.]. It might be helpful just to use that as an example. For example, if there are different AEC detectors for different-size buckies [ph.], that might be instructive.

DR. MONSEES: Is there any other comment on that?

MR. PIZZUTIELLO: No.

DR. MONSEES: Okay.

So then, let's move down to the kVp question.

"Does this regulation require that kVp be within 5 percent agreement with an absolute standard or within 5 percent agreement with the field measuring instrument?" and then the

answer there.

MR. PIZZUTIELLO: That's fine.

DR. MONSEES: Okay. Then we get into all that italics, which is the reg; and then the question at the bottom is the redundant question--am I right?

MR. PIZZUTIELLO: Correct.

DR. MONSEES: Okay. Then we move into "System artifacts." Is there anything else that goes from your additional list that speaks to this?

DR. FINDER: We can just keep going. I do have a couple of questions that we can do at the end.

DR. MONSEES: Okay. "System artifacts." It is page 27. "radiation output is to be measured over a 3-second period. Can exposures of less than 3 seconds meet the requirement as long as the total output meets the requirement?"

The answer is "Yes," and it goes into it.

You have a comment on that.

MR. PIZZUTIELLO: Yes. On that particular one, I didn't think it ever came out and said what I think is the essence. If a machine can do a 3-second exposure, you make the measurement at 3 seconds, but some machines max out at about 2-1/2 seconds at 28 kVp, so in that case, I think it should say if a machine is incapable of making a 3-second

exposure, you use the exposure time that is as close as attainable to 3 seconds at 28 kVp.

DR. MONSEES: Okay. That sounds logical.

Is that okay, Dr. Finder?

DR. FINDER: Yes.

DR. MONSEES: All right. Moving on to "Decompression"--and people who are interested in compression are definitely interested in decompression. On the override status, there are quite a few questions and answers on the next page. Is there any one in particular that you want to single out and discuss?

MR. PIZZUTIELLO: I have one comment on wording.

DR. MONSEES: Yes. Which one?

MR. PIZZUTIELLO: It's the third paragraph from the bottom in the answer on page 28. In parentheses, it says: "(which may not operate in the event of a power failure)."

DR. MONSEES: This is pertaining to emergency compression release.

MR. PIZZUTIELLO: Emergency release, yes. I think we want to say "which may fail to operate in the event of a power failure." So the question is not is it designed to operate or not in the event of a power failure, but if for some reason it fails to operate. So I would just suggest changing "may not" to "which may fail to operate".

DR. MONSEES: And the answer is that "FDA recommends that all systems provide for the emergency release of patients"--we hope.

Is there anything else in any of those questions pertaining to compression release and so on?

[No response.]

DR. MONSEES: Okay. If not, we'll move on to the "Medical Physicist's Annual Survey," and there was an add-on question for that. Charlie, do you want to go through this first?

DR. FINDER: Why don't you go through the survey, and then we've got some questions about the equipment evaluation.

DR. MONSEES: Okay. We'll start with the document, and then we'll do the add-ons.

On the annual survey, there are all the italics about the surveys, and then there is some Q and A pertaining to that.

"Under the interim regulations, FDA allowed some flexibility with respect to scheduling physics surveys. Will this continue under the final regulations?"

The answer is "Yes." That only makes sense; right? They have up to 14 months.

Does anybody have any disagreement or questions?

[No response.]

DR. MONSEES: Then, the next one is on surveys performed before the institution of the final regs but inspected after, and which standards would be used. It seems to make sense.

"When conducted for the annual survey, must all the tests be performed by or under the direction of a medical physicist?"

The answer is "Yes."

Are there any problems with that?

[No response.]

DR. MONSEES: Okay. Let's got to the top of page 30, "Mammography equipment evaluations."

MR. PIZZUTIELLO: I have one comment on that one.

DR. MONSEES: Yes.

MR. PIZZUTIELLO: The very last sentence--the gist of this until the last sentence is that when a medical physicist is called to do a survey or an equipment evaluation, a preliminary report hand-delivered at the time of completion of the survey is adequate. The very last sentence says "Facilities undergoing certification for the first time need to have the final written equipment evaluation report available prior to using the unit on patients."

I am not sure what the rationale for that is. If it's okay every other place to provide a preliminary report

which says that all these tests passed versus having the final written report. That wouldn't work very well in my group because all of our reports are peer-reviewed before they go out, so we provide a preliminary report at the time of survey that says this has not been peer-reviewed, and then typically within a week to 10 days, they get the final report in the mail.

In this case, we either have to compromise our peer review, which we prefer not to do, or the facility would have to not do mammography until we could get the report to them, and I don't see that there is any benefit that is provided by giving the full report versus giving a preliminary report. Maybe there is a reason why that was put in there.

DR. MONSEES: Dr. Finder, do you know what the reason is for that?

DR. FINDER: There are several reasons for it. One is that obviously, in the general sense, we didn't want facilities to stop doing mammography while they waited for the official report and that the preliminary report would be fine in most cases.

This has to do with the fact that they have to submit this to the accreditation body to get accredited in the first place. That is part of the process. So I don't know what they are submitting. Is ACR accepting these

preliminary reports that you are sending in?

MR. PIZZUTIELLO: Actually, the process does not require a physicist's report on day one, and perhaps someone from the College could clarify the procedure.

DR. MONSEES: Would you please come to the mike?

MS. BUTLER: During the entry application part of the process for a new facility, we do not require that the physicist's report be submitted. That comes in during the full application aspect of the process, and the process goes that the entry application is submitted and then a provisional certificate is issued from FDA. So I agree with Bob Pizzutiello on the adequacy of a preliminary summary from the medical physicist in order to help the facility get going.

DR. MONSEES: Do any other accrediting bodies do that differently where this would apply?

MS. GOSSITERI: I am Kay Gossiteri from Texas. In Texas, we require all the facilities to submit their medical physicist report up front, but we accept the Pass/Fail.

DR. MONSEES: Okay. So that would be the final report?

MS. GOSSITERI: Just the Pass/Fail summary.

DR. MONSEES: The summary. Okay. So this sentence could probably come out, then. Okay.

DR. FINDER: We'll look at it.

DR. MONSEES: Okay. We need to do this add-on.
Which one was it?

DR. FINDER: There are two questions.

DR. MONSEES: "What constitutes an equipment
evaluation?" This is number 3 on the add-on.

Okay. "What constitutes an equipment evaluation?
What tests must the medical physicist perform for a
processor that has been replaced, undergone major repairs,
or is a new processor to the facility?" Do you see that in
the add-on questions? That may be in the manual, too. It's
not in the QC manual?

MR. PIZZUTIELLO: Bob Pizzutiello--

DR. MONSEES: Can we have her tell us about the
manual first, and then we'll hear from you? Yes?

MS. BUTLER: Penny Butler, ACR.

In the manual, it is not specifically recommended
what tests need to be done for every, single situation that
requires an equipment evaluation. However, most of the
tests in the manual refer to a specific aspect of the
imaging chain or the entire imaging chain, and the medical
physicists should use their medical judgment to determine
what tests are appropriate.

DR. MONSEES: Okay. Thank you.

Now, would you like to comment?

MR. PIZZUTIELLO: The question of when is a

mammography equipment evaluation performed, we have clarified that a little bit in our letter to our clients and said "It is an x-ray tube, filter, or mirror, high-voltage transformer, AEC sensor, or screen-film combination," and then we have left it up to the physicist to determine what tests need to be repeated depending on whatever the factors are--when was the last time the test was done and so on.

So we have not listed--if you like, I could suggest a grid of what tests--we do have that.

DR. FINDER: No, no. What this question deals with is the processor, not the x-ray machine.

MR. PIZZUTIELLO: Okay. The processor--that's much simpler--

DR. FINDER: And it is in the regulation that an equipment evaluation has to be done when the processor--reassembled, disassembled--

MR. PIZZUTIELLO: Complete processor overhaul; right.

DR. FINDER: A major change. Now the question is what test should be done, because it is required that something be done, and what test does the medical physicist have to do here.

MR. PIZZUTIELLO: Okay, that's the other part. We have covered that in our group, and what we say is that sensitometry must be done, and the three additional tests

would be the phantom image quality; the density of the phantom image, so that we can tell something about the speed in imaging; and an artifact analysis. So sensitometric comparison, phantom image quality, speed on the phantom, and artifacts.

I would also say that this is the kind of thing where it can happen on relatively short notice, and none of these tests that need to be performed is beyond the routine purview of the QC technologist in the performance of their duties. So what we have suggested is that these tests be performed in consultation with the medical physicist who under the regulation is responsible, but that the physical test need not be performed by the physicist going out there, because the technologist is fully capable of doing that.

The alternative would be to add significant increased cost and down time to facilities waiting for their physicist to come out to do something which the technologist is already able to do. But the physicist is in the loop because the data is communicated to the physicist, and the physicist makes the determination whether it is okay to use the new processor or not.

DR. MONSEES: It sounds appropriate. Does anybody have any comments?

Yes, ma'am?

MS. WILSON: I agree with Bob that you could

simply have a QC technologist and a copy of your QC chart showing your processor sensitometer before and after the change, and also, after scoring a phantom, submit a phantom by mail to the physicist for his approval.

DR. FINDER: Sounds great.

DR. FINDER: Well, let me just throw in a little problem that we've got, and that is in the regulations. If you look at the last sentence in the regulations, "shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist." We have defined "direct supervision of a medical physicist" as physicist in the room with the person doing it. And if we make an exception here, we have to be very, very careful that we don't make an exception for the other things that the medical physicist does; otherwise, we are going to have telephone conversations direct supervision of medical physicists. We have to be very, very careful.

So with that in mind, do you want to help us come up with a solution that fits everybody's needs here?

MS. WILSON: A facility could be down for several days waiting for a physicist to come from several hundred miles to your site to do something that is so simple as look at a phantom image and evaluate it.

DR. FINDER: I understand that. Now, can anybody come up with some solutions to avoid another problem that we

could create here? I don't want to solve one problem and create another one.

MR. PIZZUTIELLO: How about if the image is evaluated by the medical physicist, because it could be fedexed to the physicist within one day anyplace. Then the only question is the actual taking of the image. Can we live with that? I agree that it is important, and as much as this is annoying, I would not be willing to compromise every other place in the regulation where we have said things must be done by a qualified professional or under their direct supervision. If this opens up that can of worms, I think I would rather lose this battle than start another war. But if we can live with the fact that the image is evaluated by the qualified medical physicist and that the procedure is specified by the medical physicist, that would be a good second alternative.

DR. MONSEES: And it would minimize the down time.

MR. PIZZUTIELLO: Yes.

MS. WILSON: What happens if a facility uses a physicist that is in solo practice, and he is on vacation?

MR. PIZZUTIELLO: I need to address that because there are other areas where the elements of the mammography equipment evaluation are not things that can be done by anyone else other than a medical physicist, and those are real issues, like replacing an x-ray tube, which happens

with some frequency. So in that situation, any physicist in solo practice, whether they are in private practice or they are the only physicist employed at an institution, it is incumbent on that physicist to make backup arrangements. But this is different because every, single test that would be performed as part of the mammography equipment evaluation is a test that the technologist already routinely performs in another capacity. That's what makes this a little different.

DR. MONSEES: Yes?

DR. MOURAD: Wally Mourad, FDA.

You also mentioned the artifact evaluation, and that's a physicist test. The technology cannot do that. How do you propose to deal with that? You mentioned in your list the artifact test as the third test that could be done at the facility. That's a physicist test.

DR. MONSEES: With the processor, Bob--did you mention that?

MR. PIZZUTIELLO: Yes. The physicist--and I guess that's the way we do our practice which is different from the regulation--certainly, the artifact is specified to be done by the medical physicist as part of the annual survey, but it has been in the ACR Manual, the technologist section, since 1994, if my recollection is correct, saying this is an artifact test which might be useful. I don't believe it

is limited to the medical physicist.

Am I wrong on that?

DR. MOURAD: Yes, it is.

MS. BUTLER: Yes, you are wrong.

MR. PIZZUTIELLO: Thank you. We have been working with our technologists, every one of our clients, teaching them to do the artifact analysis every time we do our surveys, and they do them routinely. So I guess that's my personal experience and not the regulation.

I will say that with a new processor, it is important to do an artifact analysis. I don't think it would be sufficient to do a mammography equipment evaluation without an artifact analysis. So if FDA then says that the test must be performed by the medical physicist, maybe we are back to the physicist has to go.

DR. MONSEES: Realizing that it could be quite an inconvenience to patients and to the facility while the physicist is unavailable.

DR. FINDER: I would say the following, that if somebody after they leave the meeting has some ideas-- obviously, this is going to go out, but this question actually wasn't even in this thing. It will be going out at some point, and in the meantime, we would certainly be interested in people's thoughts on how to deal with this issue and come up with something that works.

DR. MONSEES: Okay. We have one more question under this before we move to the medical outcomes audit. We are going to do the stereotactic program review, the voluntary accreditation program discussion prior to going to the medical outcomes audit because one of our presenters is going to have to leave. So we are doing to do this one more question first, then move to the voluntary accreditation program update.

So what is the last question pertaining to this?

DR. FINDER: The question is "Must the equipment evaluation report be sent to the facility within 30 days?"

The medical survey report has a requirement that it has to be sent within 30 days. There actually is no date specification in the equipment evaluation that it has to go within 30 days. We would be interested in the Committee's opinion on whether it should also be held to that same standard of 30 days.

MR. PIZZUTIELLO: I think it should be. As you say, it is not in the regulation, but it is so similar in style and importance to the medical physicist annual survey that I couldn't see any justification for a different requirement.

DR. MONSEES: Okay. Are there any other final comments pertaining to the medical physicist survey or the annual tests?

[No response.]

DR. MONSEES: Okay. Then, what we are going to do now is leave this document for a moment and go to that part of our program. We have our presenters here, Ms. Buchalla from the ACR and Dr. Winchester representing the American College of Surgeons, to give us an update on the Voluntary Stereotactic Accreditation Programs.

It's up to you to decide who goes first.

MS. WILCOX-BUCHALLA: I am Pam Wilcox-Buchalla, with ACR.

My update is very brief. We now have a total of 439 stereotactic facilities that have applied for accreditation through the ACR voluntary program; 342 of those have completed the process and are currently accredited.

If we assume that the universe is somewhere around 2,500 to 3,000 facilities across the country, then we are really looking at somewhere between 15 to 17 percent of the sites have actually applied for accreditation. So we have not made the kind of progress we had hoped for. We are getting support from the FDA, from people presenting it at breast conferences, as well as publications in our bulletin, but it's not being heard very well at this point.

DR. MONSEES: So 15 to 17 percent have applied, and a lesser percent are accredited?

MS. WILCOX-BUCHALLA: Correct.

DR. MONSEES: Do you have anything further to report?

MS. WILCOX-BUCHALLA: No. That's it.

DR. MONSEES: Dr. Winchester?

DR. WINCHESTER: Well, we came in later in the history of this, and we have worked very closely with the American College of Radiology--"we" being the American College of Surgeons.

You will recall that the physician qualifications document went through many drafts, a lot of input from this Committee as well as the physicians out in the practicing community. That was published in our bulletin in May of 1998, and it was published in one of your venues as well. So there is agreement between the two Colleges about those qualifications to perform this as a physician.

We have consummated an Accreditation Services Agreement between the two Colleges; that was done about a year ago. This Committee expressed some interest in knowing a little more about what surgeons are doing with respect to stereotactic biopsy, and we did a national survey through the American College of Surgeons in October of 1998, and I can cover some of that if you wish.

DR. MONSEES: We'd love to hear it. If it is lengthy and you don't want to cover the whole thing, just

the highlights.

DR. WINCHESTER: Five minutes or so. We actually surveyed about 13,000 general surgeons in the United States, and in response, 4,857 completed the survey, somewhat less than most of our surveys. We asked several questions. The first question was "What percentage of your practice is limited to the evaluation of diseases of the breast?" and only about 13 percent of the respondents reported more than 50 percent. But if you looked at those who performed stereotactic core needle biopsy, the percentage was around 75 percent, so there was definitely a correlation between how much of your practice is breast surgery and those who are actually performing stereotactic core needle biopsy.

Another area of interest was of those 4,857 who responded, how many actually performed stereotactic needle biopsy, and about 25 percent--one out of four surgeons who I think represented a selected subset of respondents who had interest enough to complete the survey--I would have expected a higher percentage to be performing those, but actually, three out of four respondents did not do the procedure--only one out of four did.

How many mammograms did surgeons review with an MQSA-qualified interpreter? Less than 100 per year, 39 percent; 100 to 400 mammograms annually, 49 percent; and more than 400, 12 percent. Again, those performing

stereotactic core needle biopsy, the percentage was much higher--the number of mammograms reviewed was much higher.

One of the questions that I thought might be of interest to this Committee was, "If you are performing this procedure, are you doing it independently or in collaboration with a radiologist?" The response was about 50-50. About half the surgeons doing this are doing it with radiologists, and about half of them are doing it independently.

And then we have a number of questions related to CME. Those answers were satisfactory with respect to the personnel requirements for surgeons performing this, that their hands-on experience and so forth met the criteria outlined.

And then, finally, the question "Do you intend to participate in the voluntary accreditation process for the future?" I think it is really poorly understood, though, by most surgeons. Almost 39 percent indicated that they did not plan to participate in that; the rest of them looked like they would participate.

So we have a lot of work to do with respect to education and the importance of voluntary accreditation, but I think we are still pretty early in the process.

What else has happened? We have developed an application packet at the College of Surgeons and an

internal process for verification; review, reporting and accounting procedures. We have established a committee at the College level, a Voluntary Stereotactic Accreditation Committee, which I chair and Dr. Dowlat serves on, Dr. Israel, and Dr. C. Allen Henry. We have had three meetings, and we have had one meeting with the ACR committee within the last month or so.

We have developed and tested our stereotactic database just recently. We have identified 27 qualified surgeons to serve as instructors in ongoing CME. We have prepared slides and handouts to introduce the ACS Verification and Accreditation Program, so we are pretty early on in the educational process. And we have appointed three surgeons to serve as reviewers on the team survey with the ACR, and we have sent out 200 application packets in response to requests. So we have had 200 surgeons early on request applications.

I understand that the College of Surgeons will be doing the certification of surgeon qualifications to perform this procedure, and the American College of Radiology will do the balance of the process in terms of evaluating and certifying the facility.

That completes my report.

DR. MONSEES: So it sounds like you've got the target audience. It looks like it is showing that in fact

people who do perform stereotactic core needle biopsy are a select group--

DR. WINCHESTER: Yes.

DR. MONSEES: --and that they seem to be self-selecting if they are really breast practitioners, breast surgeons.

DR. WINCHESTER: Right.

DR. MONSEES: And of the 4,800 respondents, stereotactic core needle biopsy, so you've got about 1,200 people that you know who probably constitute most of them. With that mailing list, if you tweak that, you might be able to get higher compliance with accreditation; right?

DR. WINCHESTER: Yes.

DR. MONSEES: It sounds great; a good baseline survey.

DR. WINCHESTER: We have fewer to target than the American College of Radiology.

DR. MONSEES: Right. It might be easier for you. Are there any other comments?

DR. WINCHESTER: No.

DR. MONSEES: Are there any questions from the panel?

Yes?

MR. PIZZUTIELLO: Dr. Winchester, when a facility becomes accredited in the College of Surgeons program, they

will get a College of Surgeons certificate; is that correct?

DR. WINCHESTER: Yes.

MR. PIZZUTIELLO: And one other thing, just doing the math one more step from where you were going, Barbara. I think Dr. Winchester said about 50 percent were operating independently, and 50 percent were collaboratively. That means that in our estimate of the universe, we might be looking at roughly 1,000 facilities that are surgical facilities only?

DR. WINCHESTER: We don't really know.

DR. MONSEES: No--fewer, because they may have multiple surgeons in the same facility.

MR. PIZZUTIELLO: So it might be more like 500, just as an order of magnitude--maybe 500 facilities that are strictly surgeons?

DR. DOWLAT: I think it's better to look at it in a different way, Bob--to find out how many stereotactic units exist in the country. That's what you really want to know; I think FDA would be interested to know how many units are there and who operates them. As of last count, I think it was around 1,500--I may be wrong--but I think between the two companies that produce the tables, there are about that many tables in the country. And the proportion of half and half operating independently or collaboratively may apply to that.

Now, the numbers don't quite match, because if you are talking about 1,000 surgeons, there may be quite a number of units that are operated by the radiologist. So we could do with some numbers in order to consolidate or have a better idea of what you are trying to regulate in the future or supervisor or whatever.

DR. MONSEES: You said there were 1,500. I think Ms. Wilcox said there are 2,500 to 3,000 units; right?

DR. WINCHESTER: Dr. Dowlat is talking about tables. Tables is not everything. There are a lot of add-on units.

DR. MONSEES: You're talking about just prone tables?

DR. DOWLAT: I'm talking about dedicated stereotactic tables.

DR. MONSEES: Okay. You can do stereotactic core needle biopsy with an add-on to a mammography unit. I would presume that most of that would be done in radiology facilities. But the number is as high as 2,500 to 3,000.

DR. FINDER: The last time we looked at this issue--and it is hard to come by data--it was a little over 3,000 total. Now, how many of those are actually being used is a different question. Some of those units may just be sitting around and not being used very much. We don't know the use. But the number that we have gotten, I believe the

last time, was about 3,000, 3,300, something like that.

DR. WINCHESTER: We have data from the survey that sheds some light on that. We had 4,857 respondents, you will recall, and they were asked if they had access to a stereotactic unit, and 63 percent of them said that they did. And it asked at what location--radiology, surgery, outpatient, breast center or other--and radiology was 2,024; surgery, 248; outpatient breast center, 935; and other, 245, for a total of 3,4520--close to the number that you're talking about, Charlie.

DR. MONSEES: Good data. All right.

Yes?

MS. HAWKINS: I just wanted to express the fact that in conversation with a radiologist who is associated with the breast center or breast imaging center that is part of the Health Sciences Center on our medical school campus in Oklahoma, the radiologist there clearly felt that MQSA covered stereotactic. So when I said it did not, it took her going back and going through recent information that she had received perhaps to find out that this is not covered by the MQSA.

So I am just wondering if the discussion of the implementation of the standards and the discussion of the accreditation for stereotactic is not perhaps confusing some facilities, and they may think this is being taken care of.

DR. WINCHESTER: We have had one recent letter from one of the fellows at the College of Surgeons who was denied access to the stereotactic unit in the hospital which was controlled by the radiology group, and their local credentialing committee cited some outdated personnel requirements for performing the procedure that had been promulgated by the two Colleges.

The most recent interaction, it was clear that this surgeon clearly met all the requirements to perform the procedure. So I sent a letter, as chairman of our committee, to the surgeon and to the auditing committee, the credentialing committee at the local hospital, with a copy to a bunch of other people, and that's as far as we can take it. It's a local issue at that point.

But it seems difficult to me, and in some of the presentations I have made at some of the chapters around the country, it would seem difficult as far as I can see it if a surgeon has met the requirements that have been agreed upon by the two Colleges and the facility is accredited by the ACR, I think it's going to be very difficult for that facility to keep the surgeon out of the operation if they wish to perform it. That becomes a legal issue, I believe. But I've only had one letter, fortunately--one.

DR. MONSEES: Well, I suppose credentialing could always ask for additional requirements in a particular

facility. As long as it is applied equally to all those people, it might be perfectly legal.

DR. WINCHESTER: Sure.

DR. MONSEES: Are there any other comments from the panel?

Yes.

MR. PIZZUTIELLO: I have one comment, not on the report but on the process. In my travels, which are many, I have spoken to lots of stereotactic facilities, talking this issue up about voluntary accreditation and so on, as well as lectures, and I have to say that the response, sadly, has been: We'll worry about it when we are required to. We don't want to spend the money to get accredited.

I am disappointed to report that, but that has been pretty consistent, and it has been sort of borne out by the numbers that we see. So one question that came before this Committee a year or so ago was what about the community self-regulating, and I don't see that that has been very successful.

DR. MONSEES: Dr. Dempsey?

DR. DEMPSEY: I'd like to make a follow-up comment to Bob's comment. This is not the venue simply to put it out there. The whole question of a lot of things that is going to impact, in my estimation, pretty quickly on breast imaging is this whole question of remuneration and of funds

being expended for accreditation, site visits, inspections, paperwork, extra secretaries, and so on and so on--it goes on and on. And sooner or later, somebody is going to have to address the adequacy of remuneration for the time put in doing this kind of work, and I think the comment that you are getting simply reflects the level of frustration with that.

DR. MONSEES: Thank you very much for the update.

We do have a break due, but I'd like to go through the audit part, and maybe we can even finish before we break, but then we do have some other issues to discuss--we are not done.

Dr. Finder, can I move on?

DR. FINDER: Yes.

DR. MONSEES: Okay. "Mammography Medical Outcomes Audit," page 30. The general requirements are there in italics, and the question is: "An interpreting physician has left our facility since completing our last medical audit. Does he/she still have to be included in this year's medical audit?"

The answer is "Yes. All interpreting physicians must be included in the audit."

Then there is a question about locum tenens interpreting physician and should that person be included in the audit, and the answer is "Yes."

Does anybody disagree with that or have any comments on that? They make the point that the numbers may be small and therefore not statistically significant, but when you run the audit, you do it.

[No response.]

DR. MONSEES: Okay. "How should false negatives be included in the medical audit?"

You have to find it, and if you don't do your sensitivity because you have no access to a database, it may be very difficult to use those in a statistical way, although it probably does help to review those.

Would you like to comment?

MS. HAWKINS: Patricia Hawkins. I have a concern here, especially with the manner in which the information is to be included in the audit.

DR. MONSEES: Which part, Ms. Hawkins--the false negatives--

MS. HAWKINS: Yes, on how the false negatives should be included in the medical audit. My concern is that, as it says here, it is being left up to the facility, and they can select as to whether include in the analysis the year in which the mammogram was originally done or the year in which the cancer was discovered.

I think it is important to look in terms of the impact that this may have upon the need for additional

mammography review, a patient notification, because if these especially are tracked within the year that they were performed, and in light of the fact that cancers occur at various periods beyond that and so forth, but tracking them back to the year that the mammogram was done could basically indicate a need, or if significant numbers show up in a given year of false negatives, that may mean that it may be necessary for patient notification if significant problems are discovered during that year in which those mammograms were done.

DR. MONSEES: So your preference would be to advise that it be tracked to the year that the mammogram was done?

MS. HAWKINS: That the mammograms were done, yes.

DR. MONSEES: Are there any comments on that?
Yes?

DR. SICKLES: Ed Sickles. I understand where you are coming from, but logistically, it is quite complicated because you become aware of false negatives--most practicing radiologists become aware of false negatives--years after the mammogram was done--not the same year, often not even the next year, but maybe 3, 4, 5 years down the line.

So until one develops a track record of what is usual for a given year--and that might take 3 or 4 years--it is not going to be hard to interpret the results. But I

understand what you are trying to get at by tracking to year; I think that's a good concept, but I think it will be hard to assess the numbers that are coming in for an individual practice until we have many years' worth of cumulative experience.

We are going to be adding false negatives to 1995 for the next 5 years to come, and we won't get the ultimate number for many years down the line, because you often--or, at least the radiologic facility often doesn't become aware of the false negative until years after it is known to the patient. Obviously, false negatives are not known to the patient--sometimes they are not known to the patient for a while.

MS. HAWKINS: I know that, and the next question gets to the point of what has to be included in the audit if they were performed more than one year ago and so forth, and it addresses "reviewing films as old as 10 years." I still think that it is significant to track them back to the time that they were done, because even though there may be cancers that may not have occurred, for persons who had mammograms at a facility that has a significant number of false negatives during a time frame, I think that consumers deserve a right to know if there were problems during that year.

DR. SICKLES: Yes. To respond to that, realize

that false negative cases are infrequent relative to a whole mammography practice, and with anything that is infrequent, when you try to track something like this, just by statistical variation, you are likely to see none for a long period of time and then one and then none for a long period of time, but then you may see three, just randomly. And seeing three doesn't necessarily mean that that's a big red flag. If you saw 40, that would be a big red flag. That is why I think there is some merit in your suggestion, but I think it will take a while before we can determine action limits.

MS. HAWKINS: But it will only be those big red flags that will require physician notification, but they still may be--

DR. SICKLES: I understand what you are asking for, but I think it may be a while before FDA or any other body would have any idea of what action limits might be applied to something like patient notification.

DR. MONSEES: Certainly what is being encouraged here is a review of those films, no matter how many years out, by the radiologist. And one of the things they need to ask themselves is whether the abnormality is conspicuous, and was the quality of the images good enough. And those are the kinds of things we need to ask ourselves day in and day out.

So I think that when you review them, one should be asking those hard questions--were your films good enough to find it; is it there, and was is a miss; was there something wrong with the films, and so on.

Also, the other thing to keep in mind is that we are not mandated to follow up on all negative mammograms to see our false negative rate, and the reason is because it is impractical. The ones that we may find are anecdotal numbers; they are just the cases that we may find ourselves in a later mammogram, or maybe brought to our attention, but because we don't have connections with tumor registries all over the United States, we don't know our false negative rate for the most part. We have no idea.

So it may be the tip of the iceberg when we find a few of these false negatives. So that statistically, it may not really be telling the whole tale, and maybe the best we can get out of looking and learning from our false negatives is to just study it and see if we really missed it, show everybody in the institution the case, and then look at the quality of the exam and see maybe why it was missed.

Yes?

DR. SICKLES: Let me state that slightly differently so it is easy to understand by all of the more consumer-oriented representatives on the panel.

There are two purposes to looking at false

negatives, general purposes. One would be sort of a self-education purpose, and that is in place now. Every time we become aware of a false negative, the people involved should look at the case and figure out was there anything they could have done to make it better so that it won't happen again, or so that it is less likely to happen again. That is ongoing.

The other function, which is more tied in with something like patient notification, really can be effective only if you can track all of your false negatives, because as long as you are getting self-reported false negatives rather than tracking all of them by linking to a tumor registry, you don't know whether my false negative rate of 0.63 compares favorably or unfavorably to Barbara's false negative rate of 0.42. I may just look more carefully and find more because I am working harder at finding them; you don't know that.

So it would be very hard to kick into something like patient notification unless there were an egregious collection of false negatives that just happen to come in. In a facility, I would think that you would become aware of that if it were happening, but I just don't see getting regulation to the point of keying a patient notification until we have linkage with tumor registries.

MS. HAWKINS: And at this point, I am not talking

in terms specifically of patient notifications. I am talking about the advantage of tracking them during the time that they were taken, because as I said, there may be implications for patient notification, and we would not want to miss those times when there are implications for patient notification.

DR. FINDER: As a compromise, we may be able to put in some language to stress the importance of--whether you include it in either your analysis, that you somehow tie it to the year in which the mammogram was actually taken in some manner. I think you raise a very good point.

DR. SICKLES: I think it is an important point, and I think the facility could be instructed to do the sort of self-assessment evaluation, as they are now ongoing, but also keep a list by calendar year, or if they choose to work with something other than the calendar year, by whatever they are working with, so that they just tabulate them that way and keep a running list.

That will help build up a database; that's all it will do at this point.

DR. MONSEES: Okay. I think we're finished with that. Is there anything else on your list?

DR. FINDER: No. We are done with the list.

DR. MONSEES: Okay. Moving to "Reviewing interpreting physician," the question is "Must the lead and

reviewing physician(s) be listed as interpreting physician(s) at the facility?" Isn't this duplicative?

DR. FINDER: Yes.

DR. MONSEES: Yes, this is duplicative, and the answer is "Yes."

And then, "Consumer Complaint Mechanism."

"Does the complaint mechanism have to be posted?" Then there are some suggestions about how patients can be aware that they can make a complaint without putting up a sign that says "If you have a complaint, call this number," which may be very suggestive and may not be a good idea. I think there are some good suggestions here.

Do we have any other comments on this language that is in here?

[No response.]

DR. MONSEES: Okay. All right.

Yes?

MS. HAWKINS: I would just like to say that even though it is clear here as to what is meant, but being a consumer, I will say that I have not been in a facility where I have had any clear indication that I could file a complaint. So I think that FDA needs to be aware of that, that that is one of those things that is sort of the fine print.

DR. MONSEES: Well, I think the suggestion here

that "We care about our patients. If you have any comments and/or concerns," and so on--

DR. MENDELSON: Or compliments.

DR. MONSEES: --right--or compliments; occasionally, we like compliments, too--is a good one.

MS. BROWN-DAVIS: Carolyn Brown-Davis. You know, I'm listening to Ms. Hawkins, and she brings up a very good point. When I think back on my last three or four mammograms, I have not seen any indication, either, that if I were not pleased, I could--I happen to know what I can do--but there was no signage--not even a comment on the application or the form that one fills out.

So I am wondering that we know this, how can it be instituted--I mean, a little further than just a suggestion as to--because that's what I am understanding this is--this is how it can be nicely said--but how do you go a little further than that and actually get it done, without it being--and I understand that this is guidance here.

DR. MONSEES: I'm not sure that I necessarily want to post that in my facility, because I don't want to necessarily handle, you know, "I waited 10 minutes after my appointment time," that type of thing. You mean more substantive complaints.

MS. BROWN-DAVIS: Right. I understand what you're saying, but I also understand and agree with what Ms.

Hawkins is saying, that in many--and I am assuming that where I am getting my mammogram is probably pretty typical of where many of us are--there is not language that speaks to this is what you can do. And I understand that we don't necessarily want to state--I understood that--so when I initially read this, it sounded just fine. But I hadn't thought about the fact that I have never, ever seen an opportunity to get information on what to do should I have a complaint. Do you understand what I'm saying?

DR. MONSEES: Yes.

Dr. Dempsey?

DR. DEMPSEY: As another one of the administrative hats I wear, I am director of all the outpatient radiology at UAB, which right now is running about 10,000 exams per month, so it's pretty busy. And as such, I can tell you that any patient who has a complaint about any area knows very easily how to complain, because I am the one who screens every one of them.

It is fairly obvious--if you are in a facility, you know where you are being done, and if you have a complaint, I think any facility has a mechanism that is easily discerned to register a complaint. I'm not sure that at each area, we need to hang out a consumer complaint phone number, because I think that sends the wrong message. I think the message that your technologists, your secretaries,

your patient care assistants want to convey is that they are there for the excellent patient care; that's what you want to convey--not "Oh, by the way, your complaint can be registered with So-and-So." You can call that psychology if you will, but that's the wrong message to send. But I can tell you from personal experience at a rate of 10,000 exams per month, that if anybody in any one of our radiology areas in the outpatient facility has a complaint, they don't have any trouble registering it--guaranteed.

DR. SICKLES: As currently implemented, at least as I understand it with the new regulations, each facility has to have a procedure set up in their policy and procedure manual for complaints. Part of that procedure should--at least it is in our place--be to educate all the personnel who have contact with patients, every, single one of them from the technologists, the radiologists, the receptionist, scheduler, everybody--whenever you hear a complaint, then you tell the woman what can happen. We don't invite complaints, but everybody who comes in patient contact should know how to respond to a complaint with, you know, we'll try to solve it right then and there with the woman, and if we can't, the next step for you is to go to so-and-so. That should be written in the policy and procedure manual, and I think the inspectors are supposed to look for that.

DR. DEMPSEY: I was about to say that in our last inspection, that was very pointedly looked at, and technologists were asked if a patient has a complaint, how do they proceed. I can tell you the inspectors were looking at that regulation extremely carefully, at least in Alabama.

MS. HAWKINS: Let me ask Dr. Dempsey how many consumer complaints did you notice during the inspection?

DR. DEMPSEY: During the inspection--for a year?

MS. HAWKINS: Yes. You said you specifically looked for those--

DR. DEMPSEY: Sure.

MS. HAWKINS: --were there complaints on file from consumers?

DR. DEMPSEY: Oh, sure. In all areas of radiology in terms of mammography, it averages about one per month. As a matter of fact, I had one last month. I talked to the patient and her husband myself, and they are happy--now.

DR. MONSEES: I have to say we have more than one per month, and it generally pertains to finding the old films and that kind of thing. It's a big problem in large institutions.

MS. HAWKINS: Well, I think that will be a clear indicator, that if they are present, if there is documentation that consumers have complained, we will know the word is getting out.

DR. MONSEES: Okay. So I think we're finished with this document.

We are going to go to break--yes, Dr. Finder?

DR. FINDER: Could I just make one comment before we close?

DR. MONSEES: Yes, please. Go ahead.

DR. FINDER: Just on the document itself, I think it's a good indication that FDA has gone to this third level of guidance, that they are again consulting with the Committee for efforts to improve it, and I'd like to say that that's a good thing, and the community of radiology and the patients I think have benefitted by this.

DR. MONSEES: I think so, too, and I think that what will help even more is when these are all posted, and there is a search engine so that facilities that have particular questions about different parts of the regs can more easily find what the guidance is. That will be even more helpful than these types of documents are themselves. That search engine is goign to be very important.

All right. So we're goign to go to break, and when we come back, we have "Staes as Certifiers - Update," and we have "Final Regulation Implementatin - Problematic Issues," and then review of summary minutes, and then future meetings, and then we are done.

So let's take 15 minutes, and we'll see you at

3:15.

Thank you.

[Break.]

DR. MONSEES: Okay, folks, we're going to start back up. We're now goign to hear from Ruth Fischer, an update on States as Certifiers.

MS. FISCHER: Good afternoon. At this point in the day, I have prepared different versions of this talk. One is exciting, one is funny, one is controversial, the other is boring, so you may take your pick.

DR. MONSEES: Do we get to vote?

[Laughter.]

DR. FINDER: Did I hear that one was short?

[Laughter.]

MS. FISCHER: For the aske of our new members, I would just like to go over what the Staes as Certifiers Program actuall is before I give you its update.

[Slide.]

Subsection Q of the original statute says that FDA can delegate to States certain of its responsibilities if the State is interested and qualified to do so. And first of all, authorities that remain with FDA are the establishment of the quality standards, so therefore, should we get into interventional or digital regulations, that remains with FDA. The approval or disapproval of

accreditation bodies stays with FDA.

We collect fees in that those inspection-related services that FDA provided, we continue to collect fees for; withdrawal and approval of the State certification agencies, and then maintaining oversight of the State certification program.

[Slide.]

Those authorities that can be delegated to States are the issuing and the renewal, the withdrawal, suspension or revocation of facility certificates, the annual inspections of the facilities and the corresponding compliance and enforcement actions.

[Slide.]

Those areas in which we can maintain dual authority are in suspending or revoking certificates, the issuance of sanctions, and other enforcement actions. What this means is that in a rare instance, if there is a particularly egregious violation, FDA could if it chose to levy an additional penalty in addition to what the State does or, in an equally rare situation, if a State were to not take an appropriate action, then FDA could go in and take action against the facility. We don't anticipate those situations to occur, but it is a fallback position.

When I last spoke to you last fall, the demonstration project had just gotten under way. The States

of Iowa and Illinois were participating in this demonstration project, and we had gone through the usual sort of start-up activities. We talked about data transmission, the electronic transfer of data as being one area where we had a little rough going in the beginning. That has been completely worked out. Just like with the start-up of any program, there are those little bugs when you first begin.

[Slide.]

Amazingly enough, in 2 weeks, we will have completed the first year of the demonstration project, and I am happy to report that it has gone very well. The type of oversight that we have done has been ongoing with our State liaisons; these are the FDA folks who are on the front lines every day who communicate with the State over any of their operational activities. And Vicky Jernigan [ph.], who is doing the slides, is our liaison to the State of Iowa, and Kate Chesmoor [ph.], who is not able to be here today, is our liaison to Illinois. And I must say that the two of them have really carried quite a load this past year in contributing to the success of the program.

We are doing quarterly reports officially. We are looking at some quantitative as well as qualitative data that I will go over with you. We have conducted site visits to both States. We went to Des Moines, Iowa and

Springfield, Illinois in February--high points of the season. And the team was multidisciplinary. The State liaisons went to their respective States. They were accompanied by one of our computer specialists, Dan Trammell, who is in the audience, and Dan has been extremely helpful in working out all those electronic data transmission items. He has been very effective in interacting with the States for us.

We had Mike Devine [ph.] from the Inspection Support Branch--a number of you know Mike, who went. And we had what we call a regional radiological health representative. They oversee a certain number of States for FDA and their field people. They went along as well to the respective States. And we took a look at a variety of records. We looked at inspection records. These were targeted in that we decided to look at level 1 or level 2 findings. There were no level 1's at the time we went, so we took a look at level 2 findings to see how the State responded--if it was appropriate, if it was timely, and so forth--so we had a multidisciplinary team go out.

[Slide.]

The performance indicators that we were looking at, we modeled after the Nuclear Regulatory Commission's program--basically, technical staffing and training, information systems, inspection and compliance activities,

and certification activities are what you can distill out of that.

[Slide.]

All of these items were looked at in the applicatio, and when we went out to the States and what we are goign to take a look at now is have athe requisite number of inspections for continuing experience been met. We know that continuing education has been met. We have had ongoing talks with management about adequate staffing levelse. One of the major things we learned through the demonstration project was to look at backup personnel. If your primary program person has an illness or is on vacation, do you have somebody who not only theoretically knows the program but can actually get in there and handle the paperwork and the electronic data transmissions because mammography facilities keep coming in and out of the system, so the necessity for backup personnel was an important one.

[Slide.]

These were the criteria we took a look at for inspection and compliance activities. Ninety percent of facilities being inspected annually was a number that we drew out of our hat. Of course, the law says 100 percent, and we said for the demonstration project we'll take a look at 90, and we can adjust this number if necessary.

[Slide.]

If you take a look at the last column, we have an 8-month total; we will be preparing a year's total within the next--oh, sorry--do you have the next chart? [Pause.] At the end of 8 months, the State of Illinois had completed 56 percent of its inspections, Iowa 63 percent, and FDA 61 percent. That meant that all three of us were on target to complete 90 percent within the next 4 months, and we will check to see where we are, but we don't anticipate any problems. If everybody is up around 95 percent, then we will probably up that for the next year of the demonstration project. We are trying to find what the appropriate number is.

[Slide.]

The next is an important one. This is one in which the States excel, and that is resolving inspection findings. Iowa had resolved 100 percent of their findings within the 4-month period that we had established. As a matter of fact, Iowa does it in 2 to 5 days. Illinois had 98 percent. The only one they did not have within that time frame--it was only one facility, and it was appropriate that it was not resolved within that time frame because of equipment requirements that were coming in and so forth. Illinois has been resolving theirs in a month or less.

Now, for FDA, we will be able to have figures starting this last quarter. We had a change in our data

system and our computer system in how we record it. We will be able to record our numbers. We could give you a number, but it would not bear much accuracy. We do not have a lot of confidence in it. We will be able to do a much better job of tracking that.

Also, we don't have the same type of control that the State does in that our district offices play a large part in the resolution of these findings and timing and so forth, and as to be expected, a very large bureaucratic institution may not always be the fastest, and that has borne itself out. But we do commend the States of Iowa and Illinois for the great job that they are doing in that area.

[Slide.]

The first four bullets are things that we looked at in the application as needing to be in place before we did an approval. We take a look and make sure that it is appropriate as it goes through the year. At the time of this, there were not any FDA inspector audits since many of them are scheduled for the latter portion of the year, not the front portion of the year, so we'll be checking to see what reports come in from our auditors as part of our year-end report.

[Slide.]

With certificates, we are looking for them to be issued within 10 working days of when we notify the States

with our electronic data transmissions. We look for the States to transmit data if they have it. For example, in the State of Iowa, they don't always have something to transmit on a weekly basis.

We are looking at weekly because that is what HCFA requires for Medicare reimbursement, so it is important to have timely transmission. And then the States have effective systems to handle facility inquiries.

[Slide.]

Again, these items were looked at as part of requirements for the application, and then we continue to make sure that the processes are appropriate during the time period. It hought it woudl be interesting for you to nknow that for additional mammography review and processes for patient notification, the State of Iowa consults with its team of clinical image reviewers from its accreditation program; the STate of Illinois has a State advisory group, and many of you know Dr. Carl Viborgny [ph.], who is on that as a consultant to them.

[Slides.]

Lessons learned. We learned to look for backup personnel, and the States learned that it was really necessary to have them. And we have a circumstnace in which it is not hypothetical, where we really needed another person to be able to step in. It will help us as we

evaluate States, especially in small States, to make sure that personnel are available for this.

Also, the Davis systems training--it is not as critical that the computerer personnel know how to do it, because they grasp that immediately; it is that the program personnel be nuts-and-bolts, day-to-day people, know how to operate and transmit that data, because they are the ones who are doing it. The IT personnel are the ones who provide technical support, but they are not the people handling the data.

[Slide.]

Finally, one of the things that we have learned is that, believe it or not, the States asked us to increase our communications with them. We have very good relationships going back and forth with this program. One State said if you see a problem, don't wait until the end of the quarter to tell us about it; tell us immediately so we can work on it. It is very proactive.

Also, our performance indicators needed some tweaking, and we are in the process of completing that so it is clearer for the States to follow what it actually is that we are looking for. We had some redundant indicators.

We had no takers from the States for year 2, so we have no new States joining the program, but both Iowa and Illinois will be continuing into the second year of the

demonstration project, and now it looks like there will be a third year in that we finally have a firmer handle on the regulatory time frame. The Office of Management and Budget did tell us that they want to review States as Certifiers regulations. That adds 6 months to the process. So we are expecting that the program will be effective approximately August of 2001, but that means that by next year, people will be applying for it, and the proposed regulations were saying we will probably reach the Federal Register by end of March, beginning of April 2000. So we'll let you know.

Thanks.

DR. MONSEES: Do any of the panel member have a question for Ms. Fishcer?

Yes?

MR. PIZZUTIELLO: Bob Pizzutiello.

Just a couple of questions, Ruth. You were talking about how the responsibilities were divided up between FDA and the States. The responsibility for training inspectors resides still with FDA?

MS. FISCHER: Yes, it does.

MR. PIZZUTIELLO: Okay. So if a State is in this demonstration project, and they are bringing a new person into the system, they go and attend Course 1, 2, 3, whatever they need to, as the other inspectors?

MS. FISCHER: Correct.